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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,736	02/04/2004	David Knaack	2004367-0034	5581

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
09/02/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No.	Applicant(s)	
	10/771,736	KNAACK ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31 and 112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 and 112 are pending in this application.

Applicants' arguments filed April 10, 2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Posnansky U.S. Patent No. 2,882,249, Boyce et al. U.S. Patent No. 6,123,731 and Gunatillake et al. European Cells and Materials 2003.

Posnansky teach the formation of polyurethane with cross-linked bridges (column 2, lines 30-40) by the reaction between a polyisocyanate such as diisocyanate and hydroxy containing monobasic fatty acids (column 1, lines 15-21). It teaches the formation of inter alia, solvent resistant putties (column 2, lines 52-53). Addressing instant claim 5 Posnansky teaches m-tolylene diisocyanate (an alternate chemical name for toluene diisocyanate) as an example of a polyisocyanate that can be employed to make the polyurethane matrix (column 4, lines 54-55). Addressing instant claim 112, drawn to the combination of polyisocyanate with a biomolecule (non hydroxylated), Example 1, column 6 bridging to column 7, teaches linseed oil (not hydroxylated) combined with isocyanate.

It does not teach the addition of a reinforcement embedded in the matrix selected from bone and bone substitutes such as calcium carbonate.

Boyce et al. teach that the use of autograft bone, allograft bone or xenograft bone is well known in both human and veterinary medicine (column 1, lines 15-30) and teach the use of said osteoimplants combined with reinforcing particle, fiber, fillers and bone growth inducing substances (column 2, lines 13-17), for example, bioabsorbable polymers (column 4, lines 35-36).

Gunatillake et al. teach biodegradable synthetic polyurethanes for developing scaffolds in tissue engineering (page 1, column 2), formed by a reaction with lysine diisocyanate, (a polyisocyanate) (page 9, column 1). The prepolymers were cross-linked using 2,6 diisocyanatohexate (page 9, column). The prior art employs the same biodegradable synthetic polyurethanes, reacted with lysine diisocyanate, for developing scaffolds in tissue engineering and further comprise the addition of growth factors (page 1, column 2, last paragraph) and Boyce provides motivation to employ bone or bone substitutes with the biodegradable polyurethane scaffold. Gamma caprolactone is disclosed (page 9, column 2) which is a species of polycaprolactone. Regarding instant claims 9 and 10 drawn to further incorporation of bioactive agent, Boyce et al. teach the incorporation of suitable biostatic/biocidal agents (column 4, lines 17-50). The reference is silent regarding amount of reinforcement in the composite; however, the idea of combining reinforcement to composite material was recognized in the art as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to the polyurethane composite that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The instant claims are drawn to polyurethane wet compressive

strength of between 3 MPa and 100 MPa. Gunatillake et al. teach a MPa tensile strength of between 8 to 40 MPa. Gunatillake et al. fail to disclose the MPa tensile strength of from 50 to 100 MPa, wet tensile strength, creep rate, degradation rate, maximum shear strength, maximum resolved compressive strength and maximum resolved tensile strength, however, as noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Response to Arguments

Applicant asserts that Posnansky et al. does not teach the reaction of hydroxy containing fatty acids with polyisocyanates to form polyurethane with cross-linked bridges, but teaches the reaction of non-linear polyacidesters with polyisocyanates to form plastic materials. In response, Posnansky et al. teach the formation of **polyurethane** by treating the non-linear polyacidesters **of** a long chain hydroxy containing organic fatty acid with a polyisocyanate. It teaches that the hydroxy-

containing monobasic fatty acids, which are the starting materials of this invention may be either saturated or unsaturated and may be either naturally occurring or artificially synthesized (column 3, lines 4-8). Applicant's specification defines biomolecules as phospholipids, **fatty acid**, cholesterol, polysaccharide, starch, or a combination **or modified form** of any of the above. The fatty acids of Posnansky et al. are modified in the manner described supra and as such read on the instantly claimed "biomolecules". In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Boyce et al. is cited as providing motivation to employ bone or bone substitutes with the biodegradable polyurethane scaffold. Gamma caprolactone is disclosed (page 9, column 2) which is a species of polycaprolactone. Applicant asserts that Gunatillake et al. does not teach the use of a polyurethane made from a biomolecule as claimed. In response, Gunatillake et al. teach biodegradable synthetic polyurethanes for developing scaffolds in tissue engineering (page 1, column 2), formed by a reaction with lysine diisocyanate, (a polyisocyanate) (page 9, column 1). The prepolymers were cross-linked using 2,6 diisocyanatohexate (page 9, column). The prior art employs the same biodegradable synthetic polyurethanes, reacted with lysine diisocyanate, for developing scaffolds in tissue engineering and further comprise the addition of growth factors (page 1, column 2, last paragraph). Gunatillake et al. further teach that PLA-PGA copolymers used in bone repair applications have been shown to be biocompatible, nontoxic and

non-inflammatory (page 5, column 1, paragraph 1). Gunatillake et al. is silent regarding amount of reinforcement in the composite; however, the idea of combining reinforcement to composite material was recognized in the art as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to the polyurethane composite that was ready for improvement and the results would have been predictable to one of ordinary skill in the art. The instant claims are drawn to polyurethane wet compressive strength of between 3 MPa and 100 MPa. Gunatillake et al. teach a MPa tensile strength of between 8 to 40 MPa.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

August 29, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614